

Recommendations of the SEC (Gastroenterology & Hepatology) made in its 09th/24 meeting held on 12.09.2024 at CDSCO HQ New Delhi:

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| GCT Division | | | |
| 1. | CT/104/24 Online Submission (45016) Bl 456906 solution for injection 0.5 ml | M/s. Parexel International Clinical Research Private Limited | The firm presented phase 3 clinical study protocol no. 1404-0044, version 1.0 dated 27 May 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. |
| 2. | CT/105/24 Online Submission (45018) Bl 456906 solution for injection 0.5 ml | M/s. Parexel International Clinical Research Private Limited | The firm presented phase 3 clinical study protocol no. 1404-0064, version 1.0 dated 24 May 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. |
| 3. | CT/69/24 Online Submission (43308) Efruxifermin | M/s. KlinEra Global | The firm presented phase 3 clinical study protocol no. AK-US-001-0106, version original dated 19 March 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. |
| 4. | CT/125/23 Online Submission (34657) Ambrisentan | M/s. Nextvel Consulting LLP | The firm presented protocol amendment 1 version 2.0 dated 20 August 2024 protocol no. N-003-CRD005. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| SND Division | | | |
| 5. | SND/MA/23/000273 Ursodeoxycholic Acid Tablets IP 150mg/300mg/450mg /600mg | M/s. Abbott India Limited | In light of earlier recommendations dated 14.05.2024 and 20.06.2024, the firm presented the proposal of Ursodeoxycholic acid tablets IP 150mg/300mg/450mg/600 mg wherein they presented summary of changes and the revised Phase III protocol before the committee. After detailed deliberation, the committee opined that firm should revise the protocol with respect to the following points: 1. The firm shall define the normal ALT value for both males and females. The difference in ALT levels normalization has to be compared among the placebo arm and the test arm. And also the |

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| | | | <p>ALT reduction value shall be defined in percentage decrease from the baseline normal level.</p> <ol style="list-style-type: none"> 2. Primary and secondary objectives shall be redefined to make the study clinically meaningful outcome. The Primary end point shall include fibroscan investigation at base line and at six months of study duration and protocol shall also incorporate normalization of ALT value as endpoint. 3. Sample size: <ol style="list-style-type: none"> a. Shall be calculated based on single dose with respect to the placebo b. Shall be reworked based on the credible studies to strengthen the study objective <p>Accordingly, the firm shall submit the revised clinical study protocol to CDSCO for further review by the committee.</p> |
| FDC Division | | | |
| 6. | <p>FDC/MA/24/000145</p> <p>Vonoprazan Fumarate eq. to Vonoprazan 20mg + Domperidone IP ER 30mg uncoated bilayer Tablet</p> | <p>M/s. Hetero Labs Limited</p> | <p>The firm presented the proposal before the committee.</p> <p>After detailed deliberation, committee opined the following:</p> <ol style="list-style-type: none"> 1. The firm did not present any satisfactory scientific justification on rationality of the combination and its significant benefits. 2. The firm did not present any published literature from peer-reviewed journal w.r.t Vonoprazan along with Domperidone drug. 3. Firm did not present approval status of FDC, acid suppressants and prokinetic in any other country. Moreover, the proposed FDC is not approved internationally. 4. The firm did not present any proof of concept study in support of significant clinical need of the |

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| | | | <p>FDC in the proposed indication.</p> <ol style="list-style-type: none"> 5. The firm did not present any data/literature w.r.t Drug-Drug-Interactions (known and/or expected) among the active ingredients present in the FDC. 6. The firm has not presented any scientific literature regarding essentiality and desirability of the FDC. <p>Accordingly, the firm should submit above data for further review by the committee.</p> |
| 7. | <p>FDC/MA/24/000148</p> <p>Vonoprazan Fumarate eq. to Vonoprazan + Domperidone IP + Domperidone IP SR (10mg+10mg+20mg & 20mg+10mg +20mg) hard gelatin capsule</p> | <p>M/s. Macleods Pharmaceuticals Ltd.</p> | <p>The firm presented the proposal before the committee.</p> <p>After detailed deliberation, committee opined the following:</p> <ol style="list-style-type: none"> 1. The committee noted that firm did not present any supportive literature w.r.t. Domperidone 10mg in IR form and 20mg in SR form tablet in capsule. 2. The firm did not present any satisfactory scientific justification on rationality of the combination and its significant benefits. 3. The firm did not present any published literature from peer-reviewed journal w.r.t Vonoprazan along with Domperidone drug. 4. Firm did not present approval status of FDC, acid suppressants and prokinetic in any other country. Moreover, the proposed FDC is not approved internationally. 5. The firm did not present any proof of concept study in support of significant clinical need of the FDC in the proposed indication. 6. The firm did not present any data/literature w.r.t Drug-Drug-Interactions (known and/or expected) among the active ingredients present in the FDC. 7. The firm has not presented any scientific literature regarding |

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| | | | <p>essentiality and desirability of the FDC.</p> <p>Accordingly, the firm should submit above data for further review by the committee.</p> |
| 8. | <p>FDC/MA/24/000151</p> <p>Vonoprazan Fumarate eq. to Vonoprazan 10mg/20mg + Levosulpiride SR 75mg hard gelatin capsule</p> | <p>M/s. Eris Lifesciences Limited</p> | <p>The firm presented the proposal before the committee.</p> <p>After detailed deliberation, committee opined the following:</p> <ol style="list-style-type: none"> 1. The firm did not present any satisfactory scientific justification on rationality of the combination and its significant benefits 2. The firm did not present any published literature from peer-reviewed journal w.r.t Vonoprazan along with Levosulpiride drug. 3. Firm did not present approval status of FDC, acid suppressants and prokinetic in any other country. Moreover, the proposed FDC is not approved internationally. 4. The firm did not present any proof of concept study in support of significant clinical need of the FDC in the proposed indication. 5. The firm did not present any data/literature w.r.t Drug-Drug-Interactions (known and/or expected) among the active ingredients present in the FDC. 6. The proposed FDC is not approved internationally. 7. The firm has not presented any scientific literature regarding essentiality and desirability of the FDC. <p>Accordingly, the firm should submit above data for further review by the committee.</p> |
| 9. | <p>FDC/MA/24/000170</p> <p>Vonoprazan Fumarate eq. to Vonoprazan 10</p> | <p>M/s. Eris Lifesciences Limited</p> | <p>The firm presented the proposal before the committee.</p> <p>After detailed deliberation, committee</p> |

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| | mg/20mg + Domperidone IP 30 mg/30mg (as sustained release form) hard gelatin capsule | | <p>opined the following:</p> <ol style="list-style-type: none"> 1. The firm did not present any satisfactory scientific justification on rationality of the combination and its significant benefits. 2. The firm did not present any published literature from peer-reviewed journal w.r.t Vonoprazan along with Domperidone drug. 3. Firm did not present approval status of FDC, acid suppressants and prokinetic in any other country. Moreover, the proposed FDC is not approved internationally. 4. The firm did not present any proof of concept study in support of significant clinical need of the FDC in the proposed indication. 5. The firm did not present any data/literature w.r.t Drug-Drug-Interactions (known and/or expected) among the active ingredients present in the FDC. 6. The firm has not presented any scientific literature regarding essentiality and desirability of the FDC. <p>Accordingly, the firm should submit above data for further review by the committee.</p> |
| 10. | FDC/MA/24/000179 Vonoprazan Fumarate 20mg + Itopride Hydrochloride IP 150mg SR film coated tablet | M/s. Hetero Labs Limited | <p>The firm presented the proposal before the committee.</p> <p>After detailed deliberation, committee opined the following:</p> <ol style="list-style-type: none"> 1. The firm did not present any satisfactory scientific justification on rationality of the combination and its significant benefits. 2. The firm did not present any published literature from peer-reviewed journal w.r.t Vonoprazan along with Itopride drug. 3. Firm did not present approval status of FDC, acid suppressants and prokinetic in any other |

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| | | | <p>country. Moreover, the proposed FDC is not approved internationally.</p> <ol style="list-style-type: none"> 4. The firm did not present any proof of concept study in support of significant clinical need of the FDC in the proposed indication. 5. The firm did not present any data/literature w.r.t Drug-Drug-Interactions (known and/or expected) among the active ingredients present in the FDC. 6. The firm has not presented any scientific literature regarding essentiality and desirability of the FDC. <p>Accordingly, the firm should submit above data for further review by the committee.</p> |